

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kotewicz *et al.*

Appl. No. 10/024,149

Filed: December 21, 2001

For: **Cloned Genes Encoding Reverse
Transcriptase Lacking RNase H
Activity**

Confirmation No. 4033

Art Unit: 1652

Examiner: *To Be Assigned*

Atty. Docket: 0942.049000A/RWE/MTT

Second Supplemental Information Disclosure Statement

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. All documents were cited by or submitted to the Office in Application No. 08/798,458, filed February 10, 1997.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants also wish to bring the following information to the attention of the Examiner.

Life Technologies, Inc. (LTI) was the initial owner of related U.S. Patent Nos. 5,244,797 and 5,668,005. LTI and Invitrogen Corporation subsequently merged in September, 2000, with Invitrogen Corporation being the surviving entity. Thus, Invitrogen Corporation is now the owner of these patents as well as the present application.

On December 31, 1996, LTI filed suit against Clontech Laboratories, Inc. (Clontech) in U.S. District Court for the District of Maryland, alleging infringement of U.S. Patent No. 5,244,797. Subsequent thereto, and following issuance of the '005 patent, LTI amended its Complaint to also allege infringement of that patent.

In its defense, Defendant Clontech has raised numerous defenses, alleging, *inter alia*, that the patents are invalid and unenforceable. Cited herewith, consistent with the Federal Circuit's decision in *Critikon v. Becton Dickinson Vascular Access*, 43 USPQ2d 1666 (1997), is Defendant Clontech's Supplemental Response to Plaintiff's Interrogatory No. 13, setting forth the basis for each of Defendant Clontech's defenses, as well as certain of the documents referred to therein.

In addition, Defendant Clontech has filed motions for summary judgment alleging that the patents are (1) invalid for failure to disclose the best mode and (2) unenforceable due to inequitable conduct.

Defendant Clontech's motion for summary judgment on the issue of best mode presents the following additional alleged evidence that is not set forth with particularity in its Supplemental Response to Plaintiff's Interrogatory No. 13:

- (1) LTI's August 1987 Molecular Biology R&D Monthly Status Report states the following:

"Our best deletion mutant, pRTdR5-Bal31 #14 was transferred to E. coli N4830. Dave Clark has grown up and induced these cells. They are ready to be cracked open and the RT tested for H levels and efficiency of first strand synthesis. This mutant is our best candidate for a new RNase H minus RT to market."

- (2) William Enright, LTI's 30(b)(6) witness, testified as follows:

Q: . . . Is it correct that the enzyme which LTI was looking for would have as high a DNA polymerase activity as possible, and as low an RNase H activity as possible?

A: Yes

Q: And the 14N encoded enzyme had better characteristics in that regard than the enzymes encoded by previous plasmids?

A: Yes

- (3) In crude extract screenings performed prior to filing of patent application, 14N showed a better DNA polymerase to RNase H ratio (.01) than the clone, RV-C, disclosed in the patent (.03).

Defendant Clontech's motion for summary judgment of unenforceability presents the following additional alleged evidence that is not set forth with particularity in its Supplemental Response to Plaintiff's Interrogatory No. 13:

- (1) Mark Berninger, LTI's former in-house intellectual property manager, wrote a note to inventor Gary Gerard that reads:

The major publication threat to the RNase deficient RT patent comes from Goff, not ourselves. We should be sure to file before Goff publishes assuming we will

file (the attorneys had serious questions concerning the patentability of this invention)

- (2) In Applicant's January 30, 1990, response filed in connection with the patent application that matured into the '797 patent, Applicant asserted that "[u]ntil Applicants actually prepared a truncated reverse transcriptase enzyme, it was not known whether a molecule having DNA polymerase activity and substantially no RNase activity could actually be prepared. . . . Applicants were the first to prepare a reverse transcriptase having DNA polymerase activity and substantially no RNase H activity."
- (3) In Applicant's March 18, 1991, Request for Reconsideration, Applicant asserted that "[u]ntil Applicants actually prepared a truncated [RT], it was not known whether such an enzyme could actually be made. . . . In the intervening years between these publication dates [1978-1981] and Applicants' date of invention, no one was able to separate DNA polymerase and RNase activity."

In its motion, Clontech alleges that LTI made the foregoing statements knowing full well that Goff had succeeded in generating mutants of cloned M-MLV RT that lack RNase H activity. However, neither the Invention Disclosure Form nor the information about Goff's work was provided to the PTO. Instead, in order to gain allowance of the claims at issue, LTI intentionally suppressed Goff's work and steadfastly asserted itself to be the first and only to achieve an RT which lacked RNase H activity.

Clontech also alleged that the Applicants misled the PTO by signing the patent application oath in which they declared that they, not Goff, were the first to invent the claimed subject matter.

Finally, Defendant Clontech Laboratories, Inc. filed a motion to disqualify Applicant's litigation counsel from representing Applicant in the litigation due to an interview that the

examiner conducted with litigation counsel Peter J. Davis on September 8, 1997, just prior to the issuance of the '005 patent.¹ In that motion, Defendant Clontech Laboratories, Inc. asserted that

1. Mr. Davis did not have a power of attorney.
2. Disclosing information to the PTO only eight days before issuance guarantees that the information will not affect the issuance of the patent.
3. Late disclosure is suspicious since LTI had been aware of the information all along, and it was not disclosed during prosecution of '797 patent.
4. The Examiner no longer had jurisdiction over the case, and the interview was thus improper.
5. The interview was an attempt to purge inequitable conduct with respect to the '005 patent.
6. Mr. Davis did not leave the cited documents with examiner.
7. It is unlikely the examiner had possession of the file during the interview since it should have been at Issue Branch at that time.
8. LTI intentionally waited until after allowance before disclosing the Invention Disclosure Form.

Defendant Clontech also asserted in its motion to disqualify Applicant's litigation counsel that, with respect to an April 9, 1998 Information Disclosure Statement filed in the reexamination of a related patent, LTI consciously waited until the reexamination proceedings on the merits had been closed before submitting a copy of the interview summary record, since the IDS was filed after the Notice of Intent to Issue Reexamination Certificate had issued and more than 7 months after interview took place. Clontech also asserted that none of the underlying documentation was provided to the PTO. In addition, Clontech asserted that the submission of the interview

¹In parent application no. 08/798,458, copies of the documents that were discussed at the interview of September 8, 1997, with respect to the '005 patent, as well as other documentary evidence that came to light in the litigation, were submitted for consideration by the Examiner.

summary record in the reexamination proceeding was not only unusual, but demonstrates the high materiality of the information disclosed by Mr. Davis at the interview.

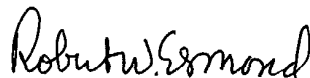
This disclosure is made in view of the Federal Circuit's decision in *Critikon*. This disclosure should not be construed as an admission that any of the information disclosed herein or herewith is material. Should the Examiner require clarification or additional information concerning any of the matters set forth herein, he is invited to contact Applicant's representative at the number indicated below.

This Second Supplemental Information Disclosure Statement is being filed more than three months after the U.S. filing date but before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: March 5, 2003

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(202) 371-2600

FORM PTO-1449 <u>SECOND SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.049000A/RWE/MTT	APPLICATION NO. 10/024,149
	APPLICANTS Kotewicz et al.	
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS		
	AT	15	Berger, S.L. et al., "Reverse Transcriptase and Its Associated Ribonuclease H: Interplay of Two Enzyme Activities Controls the Yield of Single-Stranded Complementary Deoxyribonucleic Acid," <i>Biochem.</i> 22:2365-2372, American Chemical Society (1983)

EXAMINER	DATE CONSIDERED
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AR	<u>16</u>	Dudding, L.R. et al., "Analysis of the RNA- and DNA-Dependent DNA Polymerase Activities of Point Mutants of HIV-1 Reverse Transcriptase Lacking Ribonuclease H Activity," <i>Biochem.</i> 30:10498-10506, American Chemical Society (October 1991)
AS	<u>16</u>	Gubler, U. and Hoffman, B.J., "A simple and very efficient method for generating cDNA libraries," <i>Gene</i> 25:263-269, Elsevier North Holland Press (November 1983)
AT	<u>16</u>	Hizi, A. et al., "Mutational Analysis of the Ribonuclease H Activity of Human Immunodeficiency Virus 1 Reverse Transcriptase," <i>Virology</i> 175:575-580, Academic Press, Inc. (April 1990)

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AR	<u>17</u>	Houts, G.E. et al., "Reverse Transcriptase from Avian Myeloblastosis Virus," <i>J. Virol.</i> 29:517-522, American Society for Microbiology (February 1979)
AS	<u>17</u>	Kanaya, S. et al., "Identification of the Amino Acid Residues Involved in an Active Site of <i>Escherichia coli</i> Ribonuclease H by Site-directed Mutagenesis," <i>J. Biol. Chem.</i> 265:4615-4621, American Society for Biochemistry and Molecular Biology, Inc. (March 1990)
AT	<u>17</u>	Mizrahi, V. et al., "Site-directed mutagenesis of the conserved Asp-443 and Asp-498 carboxy-terminal residues of HIV-1 reverse transcriptase," <i>Nucl. Acids Res.</i> 18:5359-5363, Oxford University Press (September 1990)

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	AR	<u>18</u>	Repaske, R. et al., "Inhibition of RNase H Activity and Viral Replication by Single Mutations in the 3' Region of Moloney Murine Leukemia Virus Reverse Transcriptase," <i>J. Virol.</i> 63:1460-1464, American Society for Microbiology (March 1989)
	AS	<u>18</u>	Schwartzberg, P. et al., "Construction and Analysis of Deletion Mutations in the pol Gene of Moloney Murine Leukemia Virus: A New Viral Function Required for Productive Infection," <i>Cell</i> 37:1043-1052, Massachusetts Institute of Technology (July 1984)
	AT	<u>18</u>	Tanese N. and Goff, S.P., "Fine-Structure Mutational Analysis of the Reverse Transcriptase Domain of Moloney Murine Leukemia Virus," <i>RNA Tumor Viruses</i> , Cold Spring Harbor Laboratory, Cold Spring Harbor, New York (May 19-May 24, 1987)

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	AR	<u>19</u>	Telesnitsky, A. and Goff, S.P., "RNase H domain mutations affect the interaction between Moloney murine leukemia virus reverse transcriptase and its primer-template," <i>Proc. Natl. Acad. Sci. USA</i> 90:1276-1280, National Academy of Sciences (February 1993)
	AS	<u>19</u>	"Defendant's Supplemental Response to Plaintiff's Interrogatory No. 13," dated May 15, 1998 from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
	AT	<u>19</u>	Letter dated October 9, 1987 from John E. Donelson, Exec. Editor of Nucleic Acids Research, Exhibit LTX 6402 from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080

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	AR	20	Referee's Report on Kotewicz' et al., "Isolation of cloned Moloney murine leukemia virus . . .," Exhibit LTX 6403 from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
	AS	20	Referee's Report on Kotewicz' et al., "Isolation of cloned Moloney murine leukemia virus . . .," Exhibit LTX 6404 from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
	AT	20	Letter dated November 17, 1987, from Gary F. Gerard, Ph.D., Director Enzymology, Nucleic Acids & Recombinant DNA, Molecular Biology R&D, of Bethesda Research Laboratories, Life Technologies, Inc., Exhibits LTX 6405 and LTX 6406 in <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080

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	AR	<u>21</u>	"Approval of Scientific Publications" form, Michael L. Kotewicz, requestor, dated July 24, 1987, with note attached, Exhibits LTX 6407 and LTX 6408 from Life Technologies, Inc. v. Clontech Laboratories, Inc., U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
	AS	<u>21</u>	Memorandum from Dietmar Rabussay dated August 18, 1987, Exhibits LTX 6409 and LTX 6410 from Life Technologies, Inc. v. Clontech Laboratories, Inc., U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
	AT	<u>21</u>	Defendant's "Answer" dated January 24, 1995 from Life Technologies, Inc. v. Promega Corporation, U.S. District Court for the District of Maryland, Civil Action No. AW 94-2776

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	AR	22	"Consent Judgment" dated March 31, 1995 from <i>Life Technologies, Inc. v. Promega Corporation</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 94-2776
	AS	22	Defendant's "Answer and Counterclaim" dated February 6, 1995 from <i>Life Technologies, Inc. v. Stratagene, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 94-2777
	AT	22	"Memorandum Opinion" dated July 27, 1995 from <i>Life Technologies, Inc. v. Stratagene, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 94-2777

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	AR	<u>23</u>	"Order" dated July 27, 1995 from Life Technologies, Inc. v. Stratagene, Inc., U.S. District Court for the District of Maryland, Civil Action No. AW 94-2777
	AS	<u>23</u>	"Stratagene's Responses and Objections to Plaintiff's Second Set of Interrogatories to Defendant and Second Request for Production of Documents and Things" dated August 7, 1995, from Life Technologies, Inc. v. Stratagene, Inc., U.S. District Court for the District of Maryland, Civil Action No. AW 94-2777, including (a) Weis, J. Virol. 45:859-863 (1983); (b) Rho & Gallo, Cancer Letters 10:207-221 (1980) and (c) Rho, Korean Journal of Zoology 22:141-152 (1970)
	AT	<u>23</u>	Defendant's "Amended Answer and Affirmative Defenses" dated July 11, 1997 from Life Technologies, Inc. v. Clontech Laboratories, Inc., U.S. District Court for the District of Maryland, Civil Action No. AW-96-4080

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AR	24	"Life Technologies, Inc., Invention Disclosure Form" dated April 30, 1987, Exhibit Nos. LTX32497-LTX32502, from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW-96-4080
AS	24	Handwritten note by Brian Schmidt, employee of Life Technologies, Inc., Exhibit LTX35171 in <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Civil Action No. AW 96-4080
AT	24	"Complaint" dated December 22, 1998, from <i>Clontech Laboratories, Inc. v. Life Technologies, Inc.</i> , U.S. District Court for the District of Delaware, Civil Action No. 98-750.

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FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.049000A/RWE/MTT	APPLICATION NO. 10/024,149
	APPLICANTS Kotewicz et al.	
	FILING DATE December 21, 2001	GROUP 1652

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	25	"Memorandum Opinion" and accompanying "Order" dated February 18, 1999, from <i>Life Technologies, Inc. v. Clontech Laboratories, Inc.</i> , U.S. District Court for the District of Maryland, Southern Division, Civil Action No. AW-96-4080.
AS		
AT		

EXAMINER	DATE CONSIDERED
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